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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,743	05/09/2001	James Nolan	00-388-A	4067

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EXAMINER	
SOROUSH, LAYLA	
ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/851,743	NOLAN ET AL.	
	Examiner	Art Unit	
	LAYLA SOROUSH	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-16,18-26,28-31 and 33-45* is/are pending in the application.

4a) Of the above claim(s) *8-12,20-24,* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,7,13-16,18,19,25,26,28-31 and 33-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on October 6, 2008 has been entered.

The original restriction election is carried over from the response to the office action mailed on October 2, 2002.

The following new rejections have been made:

Claim Rejections - 35 USC § 112

Claims 1-4, 6-7 and 36-40 recites the limitation "or another external body surface" in part (d). There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-4, 6-7, 13-16, 18-19, 25-26, 28-31,33-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakano et al. (EP 043025 A2) in view of Banknieder et al. (US Patent 4,751,243 –previously presented)

The claims are directed to methods of identifying a compound for treatment of wounds to dermis or epidermis of external body surface in a diabetic animal. The method comprises producing a wound at a site of interest, expose the wound topically to an aldose reductase inhibitor, and assess the rate of wound healing efficacy of another compound against the employed aldose reductase inhibitor.

Nakano et al. teaches the external treatment of dermal wounds comprising as a primary ingredient a compound having an aldose reductase inhibitory activity. The compounds are also used for internal treatment (page 2 lines 1-5). The reference teaches in pharmacological test Example 2, S.D. rats were fed with 30% galactose-containing powder feed for 4 weeks. After the lapse of 4 weeks their skins were grained and torn off over an area of 1 cm2. The test groups of animals were applied with an ointment having a preparation of the aldose reductase inhibitory compound for one week. The cure degree was estimated by comparing the dermal strength of the wounds with an average strength of the control group (i.e.page 6 lines 50-58 and page 7 lines 1-20). The creams were also tested on humnas (see page 8 lines 50-55).

Although, Nakano et al. teaches aldose reductase inhibitors are useful in treating diabetic complications (see page 2 lines 11-12) the reference fails to

specifically teach treatment of patience with diabetes and the use of use punch biopsy to produce the wound.

Banknieder discloses methods of improving wound healing by administering an effective amount of tolerstat, which is an aldose reductase inhibitor compound to a patient. (abstract). Bankneider discloses methods of identifying the efficacy of tolerstat as a compound for healing wounds in diabetic rats against controlled subjects. (see col 2, line 13-col 3, line 20). Bankneider created a wound in diabetic animal models, treated the animals with controls, regular diet and tolerstat doses and subsequently determined that rats that were treated with had improved wound healing (see entire col 2-3; claims 1-5). The wounds created by Bankneider is on the skin and thus on the dermis or epidermis of the subjects. The controls and regular diet of Bankneider's Group III meets the limitations of the instant claim 2 and 14 of comparing wounds in the presence of a test compound, because at least the instantly recited test compounds encompass the regular diet of Bankneider. Bankneider further claims methods of treating human with wounds from diabetes mellitus.

It would have been also obvious to one of ordinary skill in the art at the time of invention to practice Nakano et al.'s method by administering an aldose reductase inhibitor topically to a site of interest on the skin in patients with diabetes because Nakano teaches aldose reductase inhibitors are useful in treating diabetic complications (see page 2 lines 11-12), and Banknieder discloses methods of improving wound healing by administering an aldose

reductase inhibitor compound in diabetic rats. One of ordinary skill in the art would have had a reasonable expectation of success in improving wound healing by administering an aldose reductase inhibitor compound to a diabetic rats.

In addition, absence of a showing unexpected results, it would have been obvious to one of ordinary skill in the art at the time of invention to treat a wound in respective studied subjects by any known mechanism of producing a wound, such as punch biopsy, because the ordinary skill in the art would have expected to see the same results in any type of skin wound created on the skin.

The limitation of measuring the wound size is envisaged by a skilled artisan, because a parameter is needed in order to compare resulting wound healing.

Response to Arguments

Applicant's arguments with respect to claims 1-4, 6-7, 13-16, 18-19, 25-26, 28-31,33-46 have been considered but are moot in view of the new ground(s) of rejection.

With respect to Applicants argument that it is well known that systemic administration of a compound is not the same as topical administration, the Examiner points to the new rejection above wherein the aldose reductase inhibitor are useful for external (topical) treatment as well as internal (systemic) treatment.

Conclusion

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Layla Soroush whose telephone number is (571)272-5008. The examiner can normally be reached on Monday through Friday from 8:30 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SREENI PADMANABHAN/
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